

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/BE2004/000111

International filing date (day/month/year)
04.08.2004

Priority date (day/month/year)
05.08.2003

International Patent Classification (IPC) or both national classification and IPC
A61K9/52, A61K9/36

Applicant
GALEPHAR MF

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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10/567407

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/BE2004/000111

IP20 Rec'd PCT/PTO 06 FEB 2006

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/BE2004/000111

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	5-7,14,18,20,21
	No: Claims	1-4,8-12,15-17,19
Inventive step (IS)	Yes: Claims	
	No: Claims	1-21
Industrial applicability (IA)	Yes: Claims	1-21
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

PCT/BE2004/000111

V. Re Item V**Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1 Reference is made to the following documents:

- D1: WO 01/56609 A (DIERKES JUTTA ; LULEY KLAUS (DE); WESTPHAL SABINE (DE)) 9 August 2001 (2001-08-09)
D2: DE 199 10 682 A (DIERKES JUTTA ; LULEY CLAUS (DE); WESTPHAL SABINE (DE)) 21 September 2000 (2000-09-21)
D3: DIERKES JUTTA ET AL: "Vitamin supplementation can markedly reduce the homocysteine elevation induced by fenofibrate" ATHEROSCLEROSIS, vol. 158, no. 1, September 2001 (2001-09), pages 161-164, XP002288439 ISSN: 0021-9150
D4: WO 03/013501 A (SERENO ANTONIO ; SMB SA LAB (BE); BAUDIER PHILIPPE (BE); VANDERBIST FR) 20 February 2003 (2003-02-20)

2 INDEPENDENT CLAIM 1

- 2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.
Document D1 discloses (the references in parentheses applying to this document):
Capsules comprising fenofibrate 200 mg, folic acid 0.65 mg, vitamin B12 0.05 mg, vitamin B6 6 mg (p. 1, l. 13 - p. 2, l. 13; p. 8, l. 5-15).
- 2.2 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.
Document D2 discloses (the references in parentheses applying to this document):
A combination compositions comprising a fibrate (beza-, belco-, feno-, clofibrate) and one or more from cobalamin, folic acid, vitamin B6, betaine and N-acetylcysteine (c. 1, l. 50 - c. 2, l. 32; cl. 1,2).

3 DEPENDENT CLAIMS 2-21

Dependent claims 2-21 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT). Document D3 discloses a treatment involving the administration of micronized fenofibrate (200 mg /day) and a vitamin supplement comprising folic acid (0.65 mg), vitamin B12 and vitamin B6 (D3, abstract; p. 162, left hand col, l. 6-10; p. 163, par.1). Document D4 discloses capsules comprising fenofibrate and polyglycerides (Gelucire 44/14) (D4, p. 5, l. 13-26; examples).

VIII. Re Item VIII

Certain observations on the international application

- 4 The term "homocysteine lowering agent" being an essential feature of the invention encompasses potentially a great number of compounds that cannot be identified without undue burden. However, the present application provides support for only a few compounds, namely folic acid, vitamin B12, vitamin B6 and betaine. Consequently, claims 1,17 and 22 lack clarity and support according to Art. 6 PCT.
- 4.1 Plasma levels vary individually as a function of the patient tested. Therefore parameters directed to the plasma level or absorption profile to be achieved by the administration of a medicament can not form a basis for a claim fulfilling the requirements of Article 6 PCT with respect to clarity. Claim 15 does therefore not fulfill the requirements of Article 6 PCT.
- 4.2 Claim 16 does not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The claim attempts to define the subject-matter in terms of the result to be achieved, which merely amounts to a statement of the underlying problem, without providing the technical features necessary for achieving this result.